

§ 19.21

Drug Administration that are forwarded to it by: (1) The Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Ethics and Program Integrity, Office of Management and Operations, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Management and Operations for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(c) All general policy relating to conflicts of interest shall be established in guidance documents pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Division of Freedom of Information, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of per-

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sonal privacy in violation of § 20.63 of this chapter.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 55 FR 1404, Jan. 16, 1990; 65 FR 56479, Sept. 19, 2000; 76 FR 31469, June 1, 2011]

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Office of Internal Affairs, Office of the Commissioner, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR parts 73 or 73a or of any statute listed in appendix A to 45 CFR part 73 should report such information directly to the Office of Internal Affairs. Any such reports shall be in writing or shall with the assistance of the Office of Internal Affairs, be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Office of Internal Affairs, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 60 FR 47478, Sept. 13, 1995]

Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee,